IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#14

In re application of:			
Timothy W. CONNER *et al.*		Art Unit:	1631
Appln. No.:	09/333,534	Examiner:	A. Marschel
Filed:	June 14, 1999	Atty. Docket:	16517.001/38-21(15404)B
For:	Nucleic Acid Molecules and Other Molecules Associated with Plants		

APPELLANTS' BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-identified patent application. A Notice of Appeal was filed on March 1, 2002. The statutory fee of $320.00 for submitting this Brief is included in our attached Check No. **201058**. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto Company is a subsidiary of Pharmacia Corporation, located at 100 Route 206 North, Peapack, New Jersey 07977.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

fee on #13

3. Status of Claims

Claim 1 is pending. Claims 2-7 were withdrawn from consideration by the Examiner and subsequently cancelled by Applicants, and are not under appeal. Claim 1 is independent. Claim 1 stands finally rejected under 35 USC §§ 101, and 112, first paragraph. Applicants appeal all of the rejections of claim 1.

4. Status of Amendments

In the Final Office Action ("Final Action"), the Examiner has objected to the disclosure of the specification "because it contains embedded hyperlinks". December 3, 2001 Final Action (Paper No. 11) ("Final Action") at page 7. Applicants have amended the specification to obviate the objection in order to clarify the issues on appeal. *See* Amendment After Final Rejection (filed herewith). Applicants have not filed any other Amendments in response to the December 3, 2001, Final Office Action.

5. Summary of Invention

The invention is directed to nucleic acid molecules, and in particular to ESTs, that enable the acquisition of genes which encode an *Arabidopis thaliana* protein. More specifically, the invention is directed to a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10. Specification at page 9, lines 24-27.

6. Issues

The issues on Appeal are:

(a) whether claim 1 is unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claim 1 is unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claim 1 is unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description.

7. Grouping of Claims

Independent claim 1 remains in this case. No other claims are pending, therefore claim 1 does not stand or fall with any other claims. The patentability of claim 1 is addressed in Section 8.A through 8.D below. A copy of the claim on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Applicants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of polymorphisms. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because Applicants have proven that the claimed nucleic acid molecules work for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112, first paragraph, has been met.

Furthermore, Applicants have provided an adequate written description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genus of claimed nucleic acid molecules, *i.e.*, nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO: 1 to SEQ ID NO: 10, has been described by the recitation of a common structural feature, *i.e.*, the nucleotide sequences of SEQ ID NO: 1 to SEQ ID NO: 10, which distinguish molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of the invention, and have

provided an adequate description of the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

B. The Claimed Nucleic Acids Have Legal Utility

Claim 1 was erroneously rejected under 35 U.S.C. § 101 as allegedly not being supported by either a "specific asserted utility" or a "substantial utility." Final Action at pages 2-5. More particularly, the Final Action reiterates the rejection in the June 5, 2001, Office Action, which asserts that the "claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of the nucleic acid are not specific and are generally applicable to any nucleic acid. . . Further, the claimed nucleic acid compound is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter." Office Action mailed June 5, 2001 (Paper No. 8), at page 5.

The Examiner's analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real

world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 37, line 23 through page 45, line 15 and at page 45 line 16 through line 26. Either of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicants have asserted in the specification that the claimed nucleic acid molecules[1] are themselves useful for the utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms, and as hybridization probes for expression profiling. The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to co-suppress an endogenous protein. Specification at page 78, line 24 through page 80, line 2. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay,

[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

which has a legally sufficient utility.[2] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[3] and use as molecular markers.[4]

The Examiner has likewise acknowledged these and several other uses are disclosed and described in the specification. *See* Office Action mailed June 5, 2001, at page 5. Any of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecule to identify the presence or absence of a polymorphism. Specification at page 37, line 23 through page 45, line 15. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

---

[2] *See, e.g.*, MPEP § 2107.01 at page 2100-32.

[3] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify " 'real world' context or use." *See* Office Action mailed June 5, 2001, at page 6. It is a **use** of the claimed nucleic acid molecules in a real world context.

[4] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

Many of the disclosed utilities in this case, including this utility, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting the these uses are not "useful" because they are not specific and "generally applicable to any nucleic acid." *See* Office Action mailed June 5, 2001, at page 5. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

The Examiner further contends the Applicants lack a "factual basis for the determination of even a single polymorphism" and that further research is needed to investigate "whether any polymorphisms are determinable by the claimed nucleic acids". Final Action at page 3. However, use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

---

[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

Moreover, despite the Examiner's allegation, he fails to meet the "the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original). Here, the specification clearly asserts that the claimed invention is useful for identifying the presence or absence of a polymorphism. In response, the Examiner has made the conclusory statement that more research would be needed to establish this utility, but fails to state why one skilled in the art would reasonably doubt the asserted utility and why additional research would be needed.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because they "are not particular or specific to the nucleic acids being claimed." Office Action mailed June 5, 2001, at page 5. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications such as to isolate nucleic acid molecules of other plants and organisms such as alfalfa, rice, potato, cotton, oat, rye, barley,

maize, wheat, soybean, *Brassica*, etc.[6] Specification at page 34, lines 4 through 9. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Further, Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 35, line 17 through page 36, line 6. The Final Action denigrates that utility when it asserts that it is "generic" and illustrates the "non-specificity of applicants asserted utility". Final Action at page 4.

In short, the Final Action appears to be arguing that the utility is not a legal utility simply because other molecules can be used for the same purpose, *i.e.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v.*

---

[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicant to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

Chakrabarty, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in *Arabidopsis thaliana*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or insubstantial under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing "real world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (CCPA

1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (CCPA 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and

---

[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (CCPA 1974).

development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a).

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated September 21, 2001 at page 4, lines 8 through 15. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the

---

[8] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has also been challenged. Claim 1 was erroneously rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 5-6. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection is improper and should be reversed. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the SEQ ID NOs: 1-10 per se meet the written description requirement (*see* Office Action mailed June 5, 2001, at page 7), the adequacy of the written description has been challenged by the Examiner because the nucleic acid molecules of claim 1 are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 6. The bases for the Examiner's challenge are that (1) one of skill in the art would allegedly conclude that Applicants were not in possession of the claimed nucleic acid

molecules, and (2) there is allegedly "insufficient written description to support the genus encompassed by the claim". Office Action mailed June 5, 2001, at page 7; Final Action at page 6. These are not proper bases for a written description rejection of a "comprising" claim. If they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of SEQ ID NOs: 1-10, and therefore, possession of the claimed invention.

Applicants have provided the nucleotide sequences required by the claims, *e.g.*, SEQ ID NOs: 1-10, vectors comprising these nucleotide sequences, and have thus established possession of the claimed invention. The fact that the claim at issue is intended to cover molecules that include the recited sequences joined with additional sequences, or that hybridize under specific conditions to the recited sequences does not mean the Appellant was in any less possession of the

claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claim (SEQ ID NOs: 1-10), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 10, line 17 through page 12, line 5, and page 61, line 3 through page 69, line 12) and describes how to make the nucleotide sequences and the libraries from which they were originally purified. *See* specification at page 1, line 14 through page 5, line 6, and Example 1. Furthermore, the addition of extra nucleotides or detectable labels to the claimed nucleotide sequence (SEQ ID NOs: 1-10) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[10] in particular at page 15, lines 20-24 (describing sequences with labels to facilitate detection), page 27, line 21 through page 31, line 17 (describing fusion nucleic acid molecules), page 3, lines 4-16 (describing automated nucleic acid synthesizers that can be used to build nucleic acid molecules), and page 81, lines 6-14 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

---

[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[10] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

(2) Applicants Have Described the Claimed Invention

The Examiner reiterated and maintained that because Applicants have not disclosed sequences from other species with corresponding encoding fragments, mutated sequences, allelic variants, splice variants, sequences that have a degree of identity", Applicants have not adequately disclosed the claimed genus. Office Action of June 5, 2001, at page 7; Final Action at page 6. The Examiner also responds the Applicants' arguments that such related nucleic acid molecules are readily envisioned by one of ordinary skill in the art by asserting that "such apparent or obvious inventions have been indicated as lacking written description". Final Action at page 6. In support if his position, the Examiner relies on *In re Winkhaus*, 527 F.2d 637, 188 U.S.P.Q. 129 (C.C.P.A. 1975) and *In re Smythe*, 480 F.2d 1376, 178 U.S.P.Q. 279 (C.C.P.A. 1973).

The cases relied upon by the Examiner are inapplicable to the present situation. In *Winkhaus*, the specification was inadequate to meet the written description requirement because the step relied upon by the Applicants in that case was neither disclosed in the application nor was it indicated that one of ordinary skill in the art would understand that such a step was possible. *See Winkhaus* at 131. In contrast, Applicants' detailed specification incorporates several references which not only include methods known to obtain the variants of the claimed SEQ ID NOs, but further indicate that one of ordinary skill in the art would readily envision these variations. Moreover, the *Smythe* court explicitly stated with respect to satisfying the written description requirement that "[e]ach case must be decided on its own facts" and the determinative question is what the disclosure conveys to one of ordinary skill in the art. *Smythe* at 284.

The Examiner appears to argue that each nucleic acid molecule within the claimed genus must be described by its complete structure. Office Action mailed June 5, 2001, at page 8. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that

members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

The claimed nucleic acid molecules are a genus of nucleic acid molecules having a common structural feature of a particular enumerated nucleotide sequence, *i.e.*, SEQ ID NOs: 1-10. The respective common structural feature (the nucleotide sequence) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the one of the nucleotide sequences SEQ ID NO: 1-10, then it is a member of the claimed genus of nucleic acid molecules comprising at least one of those nucleic acid sequence. If a nucleic acid molecule does not contain at least one of SEQ ID NO: 1-10, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains at least one of the nucleotides SEQ ID NO: 1-10 or it does not. [11] One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences.

[11] The same argument applies to each of the other genera, for example, if a fusion construct contains the nucleotide sequence of SEQ ID NO: 4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: May 1, 2002

Lawrence M. Lavin, Jr. (Reg. No. 30,768)
by June E. Cohan
(Registration No. 43,741)
David R. Marsh
(Registration No. 41,408)

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)

MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile

APPENDIX A
Pending Claim 1

1. A substantially purified nucleic acid molecule that encodes a *Arabidopis thaliana* protein comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10.